

PETITION FOR CERTIFICATE OF CORRECTION Address to: Mail Stop Certificate of Correction Branch Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket	PALO-004
	First Named Inventor	YUN, ANTHONY
	Patent Number	7,676,269
	Issue Date	March 9, 2010
	Application Number	10/748,976
	Filing Date	December 29, 2003
Title: <i>"Treatment of Female Fertility Conditions Through Modulation of the Autonomic Nervous System"</i>		

Sir:

Transmitted herewith for filing is a Certificate of Correction for the above-identified patent. The Certificate of Correction is to correct a typographical error in the Claims section of the Patent as follows:

In Claim 13, Section 38, line 48, replace the word "acetylcholine" with the word **acetvleholine**.

Enclosed is a copy of the original claim set of the Application as filed on December 29, 2003 showing the correct information. *Also enclosed is a copy of the named section of the issued patent showing the typographical error.*

It is believed that no fee is due since the error was made by the Patent and Trademark Office. However, the Commissioner is hereby authorized to charge any fees under 37 C.F.R. § 1.20, which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815 order number PALO-004.

Respectfully submitted,
 BOZICEVIC, FIELD & FRANCIS LLP

By: /Bret E. Field, Reg. No. 37,620/
 Bret E. Field
 Registration No. 37,620

BOZICEVIC, FIELD & FRANCIS LLP
 1900 University Avenue, Suite 200
 East Palo Alto, California 94303
 Telephone: (650) 327-3400
 Fax: (650) 327-3231

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

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PATENT NO. : 7,676,269
APPLICATION NO.: 10/748,976
ISSUE DATE : March 9, 2010
INVENTOR(S) : YUN, ANTHONY JOONKYOO

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Claim 13, Section 38, line 48, replace the word
"acetyicholine" with the word acetylcholine.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303

WHAT IS CLAIMED IS:

1. A method of treating a female subject for a fertility condition comprising modulating at least a portion of the autonomic nervous system of said female subject to increase the sympathetic activity/parasympathetic activity ratio of said subject, in a manner effective to treat said female subject for said fertility condition.
2. The method of Claim 1, wherein said modulation is performed during at least one predetermined phase of said subject's menstrual cycle.
3. The method of Claim 2, wherein said predetermined phase is the luteal phase.
4. The method of Claim 1, wherein said increase of the sympathetic activity/parasympathetic activity ratio comprises increasing sympathetic activity.
5. The method of Claim 1, wherein said increase of the sympathetic activity/parasympathetic activity ratio comprises decreasing parasympathetic activity.
6. The method of Claim 1, wherein said increase of the sympathetic activity/parasympathetic activity ratio comprises increasing sympathetic activity and decreasing parasympathetic activity.
7. The method of Claim 1, wherein said modulation is localized.
8. The method of Claim 7, wherein said modulation is localized to at least one pelvic nerve.
9. The method of Claim 1, wherein said modulation is accomplished by at least applying electrical energy to said at least one portion of said autonomic nervous system.

10. The method of Claim 9, wherein said application of electrical energy comprises electrically increasing activity in at least one portion of said autonomic nervous system.
11. The method of Claim 9, wherein said application of electrical energy comprises electrically inhibiting activity in at least one portion of said autonomic nervous system.
12. The method of Claim 1, wherein said modulation is accomplished by at least administering an effective amount of at least one pharmacological agent to said subject.
13. The method of Claim 12, wherein said at least one pharmacological agent is chosen from: beta agonists, alpha agonists, prednisone, steroids, indirect agents that include norepinephrine, epinephrine, norepinephrine, acetylcholine, sodium, calcium, angiotensin I, angiotensin II, angiotensin converting enzyme I, angiotensin converting enzyme II, aldosterone, potassium channel blockers, magnesium channel blockers, cocaine, amphetamines, ephedrine, terbutaline, dopamine, doputamine, antidiuretic hormone, oxytocin, THC cannabinoids, and combinations thereof.
14. The method of Claim 12, wherein said method comprises combining said at least one pharmacological agent with seminal fluid to provide an at least one pharmacological agent containing seminal fluid mixture and administering said mixture to said subject .
15. The method of Claim 1, wherein said method further comprises determining said sympathetic activity/parasympathetic activity ratio at least prior to said modulation.
16. The method of Claim 15, further comprising performing said modulation of said at least one portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio.
17. The method of Claim 1, wherein said method further comprises determining said sympathetic activity/parasympathetic activity ratio at least during said modulation.

18. The method of Claim 1, wherein said method further comprises determining said sympathetic activity/parasympathetic activity ratio at least following said modulation.
19. The method of Claim 1, further comprising determining the ratio of Th-1 activity/Th-2 activity.
20. The method of Claim 1, wherein said fertility condition is infertility.
21. The method of Claim 1, wherein said infertility condition is subfertility.
22. The method of Claim 1, wherein said fertility condition is early pregnancy loss.
23. The method of Claim 1, wherein said fertility condition is spontaneous abortion.
24. The method of Claim 1, wherein said fertility condition is an implantation failure.
25. The method of Claim 1, wherein said fertility condition is amenorrhea.
26. The method of Claim 1, wherein said fertility condition is luteal insufficiency.
27. The method of Claim 1, wherein said fertility condition is dysmenorrhea.
28. The method of Claim 1, wherein said fertility condition is chemical pregnancy loss.
29. The method of Claim 1, wherein said fertility condition is stillbirth.
30. The method of Claim 1, wherein said fertility condition is habitual abortion.
31. The method of Claim 1, wherein said fertility condition is endometriosis.
32. A kit comprising:

(a) at least one of: an electric energy supplying device and at least one pharmacological agent; and

(b) instructions of using said at least one of said electric energy supplying device and said at least one pharmacological agent in a method according to Claim 1.

33. The kit of Claim 32, wherein said kit comprises at least one pharmacological agent.
34. The kit of Claim 33, wherein said kit comprises a plurality of pharmacological agents.
35. The kit of Claim 34, wherein at least two of said plurality differ in at least one aspect.
36. The kit of Claim 35, wherein said at least one aspect is dosage.
37. The kit of Claim 35, wherein said at least one aspect is the type of pharmacological agents.
38. The kit of Claim 32, wherein said kit includes an electric energy supplying device.

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energy source may be implantable, and may also include one or more leads or wires for coupling the one or more electrodes to an energy source.

Devices for delivering, e.g., implanting, an electrical energy supplying device and/or a drug delivery device to a target site of a subject such as into the body cavity of a subject may also be included in the subject kits. For example, an endoscope, introducer needle, and the like may be provided.

The subject kits may also include instructions for how to practice the subject methods. For example, instructions may include how to administer the one or more pharmaceutical agents provided in the kit to treat a subject for a fertility condition by pharmacologically modulating at least a portion of the subject's autonomic nervous system. Instructions may include how to use an energy supplying device provided in the kit to treat a subject for a fertility condition by electrically modulating at least a portion of the subject's autonomic nervous system. The instructions are generally recorded on a suitable recording medium or substrate. For example, the instructions may be printed on a substrate, such as paper or plastic, etc. As such, the instructions may be present in the kits as a package insert, in the labeling of the container of the kit or components thereof (i.e., associated with the packaging or sub-packaging) etc. In other embodiments, the instructions are present as an electronic storage data file present on a suitable computer readable storage medium, e.g. CD-ROM, diskette, etc. In yet other embodiments, the actual instructions are not present in the kit, but means for obtaining the instructions from a remote source, e.g. via the internet, are provided. An example of this embodiment is a kit that includes a web address where the instructions can be viewed and/or from which the instructions can be downloaded. As with the instructions, this means for obtaining the instructions is recorded on a suitable substrate.

Some or all components of the subject kits may be packaged in suitable packaging to maintain sterility. In many embodiments of the subject kits, the components of the kit are packaged in a kit containment element to make a single, easily handled unit, where the kit containment element, e.g., box or analogous structure, may or may not be an airtight container, e.g., to further preserve the sterility of some or all of the components of the kit.

It is evident from the above discussion that the above described invention provides methods, system and kits for treating a subject for a condition caused by an autonomic nervous system abnormality in a subject which are easy to use, effective, and which may be used to treat variety of different fertility conditions. As such, the subject invention represents a significant contribution to the art.

All publications and patent applications cited in this specification are herein incorporated by reference as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference. The citation of any publication is for its disclosure prior to the filing date and should not be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention.

Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it is readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

What is claimed is:

1. A method of treating a female subject for a fertility condition, said method comprising:

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providing a female subject known to suffer from said fertility condition; and

modulating at least a portion of the autonomic nervous system of said female subject to increase the sympathetic activity/parasympathetic activity ratio of said subject in a manner effective to treat said female subject for said fertility condition, wherein said method further comprises determining said sympathetic activity/parasympathetic activity ratio at least prior to said modulation and performing said modulation of said at least one portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio.

2. The method of claim 1, wherein said modulation is performed during at least one predetermined phase of said subject's menstrual cycle.

3. The method of claim 2, wherein said predetermined phase is the luteal phase.

4. The method of claim 1, wherein said increase of the sympathetic activity/parasympathetic activity ratio comprises increasing sympathetic activity.

5. The method of claim 1, wherein said increase of the sympathetic activity/parasympathetic activity ratio comprises decreasing parasympathetic activity.

6. The method of claim 1, wherein said increase of the sympathetic activity/parasympathetic activity ratio comprises increasing sympathetic activity and decreasing parasympathetic activity.

7. The method of claim 1, wherein said modulation is localized.

8. The method of claim 7, wherein said modulation is localized to at least one pelvic nerve.

9. The method of claim 1, wherein said modulation is accomplished by at least applying electrical energy to said at least one portion of said autonomic nervous system.

10. The method of claim 9, wherein said application of electrical energy comprises electrically increasing activity in at least one portion of said autonomic nervous system.

11. The method of claim 9, wherein said application of electrical energy comprises electrically inhibiting activity in at least one portion of said autonomic nervous system.

12. The method of claim 1, wherein said modulation is accomplished by at least administering an effective amount of at least one pharmacological agent to said subject.

13. The method of claim 12, wherein said at least one pharmacological agent is chosen from: beta agonists, alpha agonists, prednisone, steroids, indirect agents that include norepinephrine, epinephrine, norepinephrine, seethyeheline, sodium, calcium, angiotensin I, angiotensin II, angiotensin converting enzyme I, angiotensin converting enzyme II, aldosterone, potassium channel blockers, magnesium channel blockers, cocaine, amphetamines, ephedrine, terbutaline, dopamine, doputamine, antidiuretic hormone, oxytocin, THC cannabinoids, and combinations thereof.

14. The method of claim 12, wherein said method comprises combining said at least one pharmacological agent with seminal fluid to provide an at least one pharmacological agent containing seminal fluid mixture and administering said mixture to said subject.

15. The method of claim 1, wherein said method further comprises determining said sympathetic activity/parasympathetic activity ratio at least during said modulation.

16. The method of claim 1, wherein said method further comprises determining said sympathetic activity/parasympathetic activity ratio at least following said modulation.

17. The method of claim 1, further comprising determining the ratio of Th-1 activity/Th-2 activity.

acetylcholine

